EQUI LASERS INCORPORATED

NOV 21 2002

Laser System Design, Application, and Manufacture

K022464 1/2

Premarket Notification [510(k)] Summary

July 22, 2002
Revised October 25, 2002

Trade Name: Equilase System

Common Name: Surgical Nd:YAG Laser

Classification Name: Powered Surgical Laser Instrument, GEX
21 CFR section 878.4810, Class II

Manufacturer's Name: Equilasers, Inc.
Address: 3350 Scott Boulevard, Unit 5,
Santa Clara, CA 95054

Corresponding Official: Richard C. Sam, Ph.D.
Title: President and CEO

Telephone: 408-588-1212 Fax: 408-588-0150

Predicate: Laserscope's Lyra Series Surgical Laser System and Accessories, K990903.

Device Description: The Equilase System consists of 6 major subsystems:

1. A laser head, where laser radiation is generated from flashlamp excitement of a laser rod in a laser resonator, and the output is focused to a point. The laser head also houses a visible laser diode (VLD). Its beam is combined with the main laser beam as a aiming light.

2. A power conditioner where the input AC power is converted to electrical energy stored in capacitors for discharge into the flashlamp.

3. A cooling system to remove excess heat from the pump chamber, which is located inside the laser head.

4. A microprocessor based controller that regulates the functions of the laser system, checks status of various sensors.

5. A membrane switch keypad for user interface and provides laser parameters readout.

6. A footswitch for activating laser action.

Intended Use: The Equilase surgical laser system is intended for use in general and plastic surgery, and dermatology.

Technological Characteristics:

Characteristics	Lyra Surgical Laser	Equilase System
Active Medium	Nd:YAG laser rod	Nd:YAG laser rod
Wavelength	1064 nm	1064 nm
Temporal Mode	Pulsed	Pulsed
Exposure Control	Adjustable Exposure Time	Adjustable Exposure Time
Spatial Mode	Multi-mode	Multi-mode
Cooling	Closed loop, internal air-to-water heat exchanger	Closed loop, internal air-to-water heat exchanger
Aiming Light	630-680 nm laser diode	640-660 nm laser diode
Controller	Micro-processor based controller	Micro-processor based controller
User Interface	LCD display	LCD display
Beam Delivery	Optical fiber, 0.22 NA	Optical fiber, 0.22 NA
Operator Firing Control	Footswitch or hand switch	Footswitch
Audible Tone during laser firing	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2002

Equilasers, Inc.
Richard C. Sam, Ph.D.
President and CEO
3350 Scott Boulevard, Unit 5
Santa Clara, California 95054

Re: K022464
Trade/Device Name: Equilase System
Regulation Number: 878.4810
Regulation Name: Powered surgical laser instrument
Regulatory Class: Class II
Product Code: GEX
Dated: October 25, 2002
Received: October 28, 2002

Dear Dr. Sam:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the

quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Tab 3

Indications For Use

510(k) Number: K022464

Device Name: Equilase System

Indications for Use:

The Equilase system, used together with a FDA cleared fiber optic delivery system, is intended for general surgical incision/excision, vaporization, ablation and coagulation of soft tissues. All soft tissues such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage, mucous membrane, lymph vessels and nodes, organs and glands, are included.

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022464

Prescription Use ✓ OR Over-The-Counter Use__
(per 21 CFR 801.109)